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Serial No.: 10/769,962

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REMARKS

This paper is responsive to the non-final Office Action mailed March 22, 2007. Claims 1 and 3-31 were pending in the application. Claim 2 has been canceled. Claims 1, 3-4, 6-9 and 12-31 have been rejected. Claims 5, 10 and 11 were objected to as being dependent on a rejected base claim, but were indicated as allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. New claim 32 has been added.

Rejections under 35 USC 102(b)

In the Office Action, Claims 12-21 were rejected under 35 U.S.C. 102(b) as being anticipated by Lester (USP 5,928,198). Applicants respectfully traverse this rejection. Lester discloses a tracheostomy tube having an obturator inserted through a bore in the tracheostomy tube. The obturator is molded from a "stiff but bendable, resilient plastics material", and includes a strap 20 of generally rectangular shape that forms the major part of the length of the obturator. The strap includes three semi-circular projections 21 that are positioned to hold the strap substantially centrally within the tracheostomy tube. (Col. 2, lines 40-50). The tracheostomy tube has a relatively blunt end that receives the bullet-shaped distal tip of the obturator. (Fig. 1).

Claim 12 has been amended to specify that the smaller diameter distal portion of the dilator has a generally cylindrical profile. This is shown, e.g., in Fig. 5 of the application. The obturator of the Lester reference, on the other hand, comprises a generally flat, or rectangular, main-body portion, or "strap." (See, e.g., reference numeral 20 in Fig. 2, and Col. 2, lines 41-56 of Lester). This arrangement is much different from the claimed arrangement of a dilator body having a smaller diameter portion with a generally cylindrical profile. In addition to the foregoing, it is noted that the tracheostomy tube of claim 12 has a tapered distal tip. The tracheostomy tube of Lester has a blunt tip (shown as reference numeral 11 in Fig. 1). Therefore, Applicants respectfully submit that claim 12 is not anticipated by the Lester reference for at least the reasons referred to herein.

New claim 32 has been added. Claim 32 depends from claims 12, and adds the limitation that the loading dilator has a central lumen extending substantially

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therethrough. (See, e.g., Application at page 8, lines 27-28; reference numeral 58 in Fig. 5). Providing a central lumen in the dilator is beneficial because it, among other things, enables the insertion device to be inserted over a wire guide. This would not be possible with the obturator of the cited Lester reference where the strap extends from the proximal to the distal end of the device.

Claims 13-21 are dependent, directly or indirectly, on independent claim 12, and include all of the limitations of claim 12. Accordingly, these claims are not anticipated by Lester for at least the same reasons that claim 12 is not anticipated. Applicants respectfully submit that at least claims 15-19 are also not anticipated by Lester for at least the following additional reasons. According to claim 15 (and claim 16 dependent therefrom), the tapered distal portion of the dilator is complementary to the tapered distal tip of the tracheostomy tube, such that a generally smooth conical insertion tip is defined thereby. As stated above, the tracheostomy tube of Lester has a blunt end, and does not include a tapered distal portion. Therefore, there is no "complementary" arrangement of tapered distal portions that forms a generally smooth conical insertion tip as claimed. In addition, with reference to claim 17 (as well as claims 18 and 19 dependent therefrom), the stepped portion 52 of the dilator 50 comprises a gripping surface. See, e.g., Fig. 6 of the application wherein stepped portion 52 is freely grippable during use. In the arrangement of Lester, the element 28 referred to by the Examiner as the grippable "stepped portion", is received within "collar" 12 of the tracheostomy tube. It is not positioned such that it can be gripped by a user during use. Thus, this internal portion is clearly not "grippable" within the meaning of the claims.

Based on the foregoing, Applicants respectfully submit that independent claim 12, as well as dependent claims 13-21 and 32, are not anticipated by Lester.

Rejections under 35 USC §102(b), or in the alternative §103(a).

Claims 1, 3 and 22-29 were rejected under 35 USC §102(b) as anticipated by, or under §103(a) as obvious over Lester.

Claim 1 is directed to a tracheostomy tube having a radially-extending flange situated at the proximal end portion of the tube. The flange is capable of being selectively attached to, and detached from, the proximal portion of the tracheostomy

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tube. The inventive tracheostomy tube is particularly advantageous when used in combination with a radially expandable introducer sheath, such as the sheath shown in Fig. 1 of the present application. When a radially expandable sheath of this type is utilized for the introduction of a tracheostomy tube that is fitted with a conventional flange that projects in the radial direction from the main body of the tracheostomy tube (visualize the radial projection of flange 15 from tube 1 of the device of Lester), the effective diameter of the tracheostomy tube resulting from the presence of the radial flange makes it difficult, if not impossible, to withdraw the sheath over the tracheostomy tube once the tracheostomy tube has been inserted through the introducer sheath and into the trachea. In this instance, the flange portion of the tracheostomy tube is situated directly in the path of the withdrawing sheath, thereby obstructing its withdrawal. By utilizing a flange that may be selectively attached to, and detached from, the proximal end of the tracheostomy tube during a tracheostomy procedure, the tube can be introduced into the trachea via the radially expandable sheath. Following placement of the tracheostomy tube, the flange can be detached from the tracheostomy tube, and the introducer sheath can simply be withdrawn in the proximal direction over the tube. Alternatively, the flange need not be attached to the tracheostomy tube at all until the tube is in place in the trachea, and the introducer sheath has been withdrawn. Since the flange is not present on the tube, there is no radially extending structure present on the body of the tube that obstructs the withdrawal of the sheath. Following withdrawal of the introducer sheath over the tracheostomy tube, the flange can simply be attached, or reattached, to the tracheostomy tube, such as by a snap-fit.

The tracheostomy tube/flange combinations in Lester do not teach or suggest this feature. Rather, as noted by the Examiner in the Office Action, Lester teaches a "movable" neck flange. There is nothing in Lester to suggest that this flange is capable of selective attachment to and detachment from the proximal end of the tube, as claimed in claim 1. Rather, it appears that the flange is simply movable or slidable in some manner at the site of its attachment to the tube. As a result, the radial extension of the flange 15 of Lester would obstruct withdrawal of the introducer sheath over the tracheostomy tube following placement of the tube in the trachea.

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The present application teaches certain advantages that may be achieved when using a flange that may be selectively attached and detached from the tracheostomy tube:

The tracheostomy tube can be conveniently inserted in proper position in the trachea using the combined tracheostomy tube/loading dilator of Fig. 6, and the radially expandable introducer sheath illustrated in Fig. 1. For insertion of the tracheostomy tube, the introducer sheath is initially introduced into a pre-dilated body opening. A dilator is then inserted as shown in Fig. 1 to provide a tracheal opening of designated size. The tracheostomy tube/loading dilator combination of Fig. 6 is then inserted through the tracheal opening. Once the tracheostomy tube is in proper position in the trachea, the introducer sheath is withdrawn.

When using a conventional tracheostomy tube having the flange attached thereto in conventional fashion, it would be difficult, if not impossible, to withdraw the introducer sheath from the body opening over the tracheostomy tube. The presence of the flange on a conventional tracheostomy tube acts to increase the effective diameter of the tracheostomy tube/dilator combination, thereby providing an obstruction to smooth withdrawal of the introducer. By utilizing a tracheostomy tube for insertion that has not yet had the flange attached, or from which the flange has been removed, axially folded or otherwise manipulated in a manner such that it no longer obstructs removal of the sheath, the introducer sheath can be readily withdrawn in an axial direction over the tracheostomy tube. Once the sheath has been withdrawn, the flange can be simply snapped, extended, or otherwise affixed to the tracheostomy tube.

Application, Page 9, line 25 to page 10, line 14.

Thus, it is advantageous to be able to remove the flange, and thereby allow the introducer to be retracted proximally over the tracheostomy tube, and thereby attach (or re-attach) the flange so that it can be placed in abutment with the skin of the patient in well-known manner. Lester neither teaches nor suggests the structure as claimed herein, nor does he provide any motivation why one skilled in the art would be led to utilize a detachable flange, as claimed.

With reference to the rejection of claim 3, Applicants respectfully request clarification of the following comment provided by the Examiner in the Office Action: "One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the attachment means (see fig. 1, 18) of Lester's because as long as a flange is present at the proximal side of the tube, the ability to prevent radial

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extension of the tube would not be affected by how the flange is attached to the tube." (Office Action, page 6). As stated above, the radial extension of the *flange* obstructs withdrawal of the introducer, and is undesirable when the introducer is being withdrawn. This is why the flange is selectively removed, and thereafter reattached after the introducer has been withdrawn. The comment concerning radial extension of the tube is not understood, and clarification is requested so that the comment can be properly addressed by the Applicants.

Claim 22, as amended, is directed to a device for percutaneous insertion into the trachea of a patient. A tracheostomy tube has a distal end portion percutaneously insertable into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted. The tracheostomy tube further has a radially extending flange capable of selective attachment to and detachment from the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. A dilator is positionable within the longitudinal passageway of the tracheostomy tube for dilating an opening in the trachea. A locking assembly is provided for locking the tracheostomy tube to the dilator during insertion of said tracheostomy tube into the trachea. As stated previously, Lester does not teach a radially extending flange capable of selective attachment to and detachment from the proximal end portion of the tracheostomy tube after the distal end portion has been inserted into the trachea. Lester neither teaches nor suggests the structure as claimed herein, nor does he provide any motivation why one skilled in the art would be led to utilizing a detachable flange, as now claimed.

Therefore, Applicants respectfully submit that claim 22 is not anticipated by, or obvious over, the Lester reference for at least the reasons referred to above. Claims 23-29 are dependent, directly or indirectly, on independent claim 22, and include all of the limitations of claim 22, including the limitation of the radially extending flange capable of selective attachment and detachment from the tracheostomy tube. Accordingly, these claims are not anticipated by, or obvious over, Lester for at least the same reasons specified above with regard to claim 22.

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Rejections under 35 USC §103(a).**Claims 4, 6, 7, 8 and 9.**

Claims 4, 6 and 7 were rejected under 35 USC §103(a) as being unpatentable over Lester in view of Montgomery (USP 4,269,184). Claim 8 was rejected under 35 USC §103(a) as being unpatentable over Lester in view of Fauza (USP 6,612,305). Claim 9 was rejected under 35 USC §103(a) as being unpatentable over Lester in view of Ranford (USP 4,235,229).

Montgomery was cited for teaching a flange having a cut-away portion. Fauza was cited for teaching a removable inner cannula. Ranford was cited for teaching an inflatable cuff on the hollow tubular body. Claims 4 and 6-9 are each dependent, directly or indirectly, on claim 1, and therefore, include all of its limitations, including the limitation of a flange capable of selective attachment to and detachment from the tracheostomy tube. None of these secondary references teaches or suggests such a feature. Therefore, claims 4 and 6-9 are allowable for at least the same reasons that claim 1 is allowable.

Claims 30 and 31.

Claims 30 and 31 were rejected under 35 USC §103(a) as being unpatentable over Lester in view of Rutter (USP 7,140,369). Claim 30 is an independent claim directed to a method of inserting a tracheostomy tube into the trachea of a patient. The method, as amended, comprises the steps of: providing a tracheostomy tube comprising a hollow tubular body having a longitudinal passageway therethrough; said tubular body having a distal end portion for insertion into the trachea, and a proximal end portion exterior to the trachea when the distal end portion is inserted, said tubular body further having a curved portion intermediate said proximal and distal end portions; inserting said distal end portion of said tubular body into said trachea; trimming an excess portion of said proximal end portion of said tubular body; and engaging a flange with said tracheostomy tube at said proximal end portion of said tubular body following insertion of the distal end portion of the tracheostomy tube.

The Examiner concedes that Lester lacks a detailed description of the claimed steps. Applicants have previously addressed the Examiner's points regarding engaging

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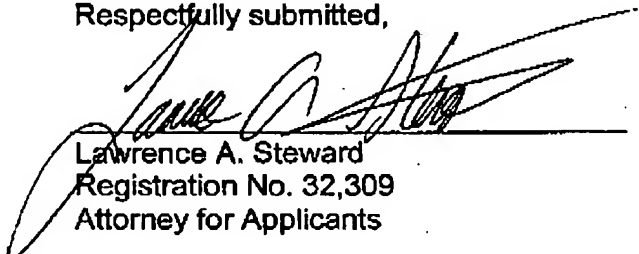
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a flange with a proximal end of the tracheostomy tube body. In claim 30, as now amended, it is clear that the flange is engaged with the tracheostomy tube after the distal end portion of the tube has been inserted into the trachea. In the tracheostomy tube of Lester, the flange is not engaged with the tracheostomy tube after the distal end portion of the tube has been inserted into the trachea. This step is possible when utilizing a device as claimed herein, since the flange is selectively attachable to and detachable from the tracheostomy tube. It is not possible with the device of Lester, without destroying or somehow reconstructing the device, since the flange is not otherwise removable from the tracheostomy tube. No teaching or suggestion of this feature is present in the cited references, either individually or in the cited combination. Therefore, Applicants respectfully submit that claim 30 is not obvious in view of the cited combination. Claim 31 is dependent on claim 30, and therefore, includes all of its limitations. Therefore, claim 31 is allowable for at least the same reasons that claim 30 is allowable.

Conclusion.

For the reasons provided hereinabove, Applicants respectfully submit that all claims 1 and 3-32 are in condition for allowance. Accordingly, Applicants respectfully request the prompt issuance of a Notice of Allowance. If the Examiner believes that prosecution may be advanced by a telephone conversation, the Examiner is respectfully requested to telephone the undersigned attorney.

Respectfully submitted,


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